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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,086	01/09/2004	David S. Lawrence	96700/860	8599

7590 02/07/2008
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EXAMINER

ROOKE, AGNES BEATA

ART UNIT	PAPER NUMBER
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1656

MAIL DATE	DELIVERY MODE
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02/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/755,086

Applicant(s)

LAWRENCE, DAVID S.

Examiner

Agnes B. Rooke

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49, 56-71, 73-80, 82-84, 86-123, 127-131, 133, 134 and 137-147 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☒ Claim(s) 89-91, 95, 97-100, 102, 122, 123, 134, 137, 142, 143, 146 and 147 is/are allowed.
- 6) ☒ Claim(s) 49, 56-69, 71, 73-78, 83, 86, 87, 88, 103-109, 112, 114, 116-119, 121, 127-129, 133, 138-141, 144, 145 is/are rejected.
- 7) ☒ Claim(s) 130 and 131 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>Nov 8, 2007</u> | 6) <input type="checkbox"/> Other: ____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 70,79,80,82,84,92-94,96,101,110,111,113,115 and 120.

DETAILED ACTION

This NON-FINAL office action is in response to the paper filed on 11/08/2007. The amendments to the claims filed on 1/08/2007 are acknowledged.

Status of claims

Claims 49, 56-69, 71-78, 83, 86-91, 95, 97-109, 112, 114, 116-119, 121-123, 127-131, 133-134, and 137-147 are under examination.

Claims 1-48, 50-55, 72, 81, 85, 124-126, 132, 135, and 136 are cancelled.

Claims 70, 79, 80, 82, 84, 92-94, 96, 101, 110, 111, 113, 115, and 120 are withdrawn.

Claims 49, 56-71, 73-80, 82-84, 86-123, 127-131, 133, 134, 137-147 are pending.

Information Disclosure Statement

The IDS submitted on 11/08/2007 is acknowledged by the examiner and is included with the instant office action.

Rejections Withdrawn

1. The rejections of claims 127 and 128 under 35 USC 112, second paragraph are withdrawn in view of the amendments to the claims.

2. The rejections of claims 49, 50, and 127 under 35 USC 102(b) as being anticipated by Khalil-Rizvi et al. are withdrawn in view of the amendments to the claims.

3. The rejections of claims 49-54, 56-58, 60-66, 72, 74, 81, 86, 87, 103, 105, 112, 117, 127, and 133-134 under 35 USC 103(a) as being unpatentable over Khalil-Rizvi et al. in view of Haugland et al. are withdrawn in view of the amendments to the claims.

Claims Allowable

Claim 89 (and dependent claims 123, 134, 137); claim 90 (and dependent claims 91, 95, 97-100, 102, 142, 143); and claim 122 (and depend claims 146 and 147) are allowable in view of the amendments to the claims.

New Objections

Claims 130 and 131 are objected to because they depend from the withdrawn claims.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 61, 62, 88, 129, 133, 140, and 141 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 61 and 62 are indefinite because they do not further define the limitations in the claims. For example, claims 61 and 62 depend from claim 60 that states that "at least a 20% change in fluorescence intensity" is produced. Further, claim 61 claims any increase in fluorescence intensity (that can be less than 20% intensity claimed in claim 60); and claim 62 claims decrease in fluorescence intensity (that can be less than 20% intensity claimed in claim 60). Therefore, the claims are indefinite.

Claim 88 is indefinite because it refers to a compound that is selected from the group of compounds set forth in Table 3. Claims 140 and 141 are included in this rejection because they depend from claim 88. See MPEP 2173.05(s) in Reference to Figures or Tables: Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted).

Claims 129 and 133 are indefinite because they depend from the canceled claims and thus lack antecedent basis to any independent claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49, 56-69, 71, 73-78, 83, 86, 87, 103-109, 112, 114, 116-119, 121, 127, 128, 138, 139, 144, and 145 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 49, 56, and 103 claim a chemical compound comprising "**a polypeptide**" where the structure of the polypeptide is not adequately disclosed in the claim. Further, "a polypeptide" can encompass any fragment of the amino acid sequence of the polypeptide. Therefore, the polypeptide claimed is not adequately described and the claims are overly broad.

The dependent claims 57-69, 71, 73-78, 83, 86, 87, 104-109, 112, 114, 116-119, 121, 127, 128, 138, 139, 144, and 145 are included in this rejection because they do not cure the deficiencies of the base claim.

Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991), states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The

compound itself is required. *See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993).*


Thus, the written description requirement is not satisfied.


Conclusion

Claim 89 (and dependent claims 123, 134, 137); claim 90 (and dependent claims 91, 95, 97-100, 102, 142, 143); and claim 122 (and dependent claims 146 and 147) are allowable in view of the amendments to the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-273-0931. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.


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KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER